

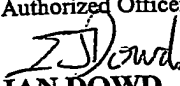
PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 30089	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001376	International filing date (day/month/year) 8 October 2004	Priority date (day/month/year) 9 October 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 002/00, C12N 005/06, 005/08, A61K 035/39, 035/407, A61P 005/48, 035/00		
Applicant MONASH UNIVERSITY et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
- a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
- ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 5 August 2005	Date of completion of the report 14 September 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  IAN DOWD Telephone No. (02) 6283 2273

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001376

Box No. I Basis of the report

With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001376

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: 10-12, 23, 26-31, 35-40, 85-92, 95-101

because:

☐ the said international application, or the said claims Nos.

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 10-12, 23, 26-31, 35-40, 85-92, 95-101

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001376

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-9, 13-22, 24-25, 32-34, 41-84, 93-94, 102-103	YES
	Claims	NO
Inventive step (IS)	Claims 1-9, 13-22, 24-25, 32-34, 41-84, 93-94, 102-103	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-9, 13-22, 24-25, 32-34, 41-84, 93-94, 102-103	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

This report is based on the documents cited in the International Search Report:

D1 WO 2003 040355

D2 *Differentiation*. 1988 Dec;39(2):139-49

Novelty and Inventive Step

D1 discloses GCTM-1, -2, -3 and -4 antigen expression from human testicular teratomas. D2 relates to a sub-population of human embryonic stem cells (HES) that have markers for GCTM-2 antigen. Neither D1 or D2 disclose GCTM-5 antibody that binds to a cell marker. The application is therefore considered to be novel. The person skilled in the art would not be lead to GCTM-5 cell marker given the presence of a related, but different, GCTM-2 marker. Therefore, the application is considered to involve an inventive step.

Industrial Applicability

All claims satisfy the requirements of industrial applicability.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001376**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 10-12, 23, 26-31, 35-40, 85-92, 95-101 are indefinite in scope and go beyond the invention as described. The inventive concept resides in the cell marker binding to a GCTM-5 antibody or active fragment thereof. The above claims are not so limited to this particular antibody. For instance, claim 10 defines a detector which identifies on the cell type a cell marker, but this marker may or may not be the same as the GCTM-5 antibody. Similar reasons apply for the remaining claims.